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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,243	11/12/2003	Solomon S. Steiner	1951300.00066	6406

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K&L Gates LLP
1900 MAIN STREET, SUITE 600
IRVINE, CA 92614-7319

EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
09/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ocipgroup@klgates.com
maria.nadal@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/706,243	STEINER ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-26 and 40-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26 and 40-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 06/05/2009 to the Office Action mailed on 03/05/2009 is acknowledged.

Status of Claims

Claims 1-22, 27-39 and 50-54 are cancelled and claims 23 and 40 are currently amended. Therefore, claims 23-26 and 40-49 are currently pending examination for patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 23-26 and 40-49 under 35 U.S.C. 103(a) as being unpatentable over Milstein (US Patent 5693338, Published 12/2/1997, Filed

09/29/1994) in view of Laube et al. (US Patent 5320094, Published 06/14/1994) **is maintained**.

Applicant Claims

Applicant claims a mircoparticulate system for drug delivery comprising microparticles of a drug and diketopiperazine having a size range between 0.5 and ten microns in a pharmaceutically carrier that is air.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Milstein teaches a delivery composition comprising an active agent, a diketopiperazine and derivatives thereof, and an enzyme inhibitor. (See column 22, claim 1). The delivery composition is a microsphere having a diameter of 10 microns. (See column 22, claims 2 and 3). The active agent can be insulin. (See column 23, claim 9). "[T]he diketopiperazines, the carriers, and thereof, the compositions of the present invention can be pH adapted to be selectively soluble in specific acidic, basic, or neutral pH ranges." (See column 7, Lines 15-20). The instant invention is particularly suited for the delivery of active agents which are subject to environmental degradation. (See column 3, Lines 1-3).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Milstein lacks a teaching wherein the microparticles are administered from a dry powder inhaler. This deficiency is cured by Laube et al.

Laube et al. teach, "The inventors have discovered that it is possible to administer insulin as an orally inhaled aerosolized medication." (See column 2, Lines 28-30). "The physical discomfort associated with subcutaneous injection of insulin causes many type II diabetic patients to refuse insulin therapy entirely, while type I patients refuse intensive treatment". (See column 1, Lines 5-8). "The method is characterized in that an aerosolized mist of small particles is produced in an associated medicament delivery chamber, the distance from the chamber to patient's mouth is set to slow the speed of aerosol particles entering the mouth and the flow rate through the chamber is regulated to a low rate ..." (See abstract).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Milstein with Laube et al. One would have been motivated to because Laube et al. teach that the least discomforting means of administering insulin. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicant's Arguments

Applicant argues that the combined references do not teach or suggest microparticles as a dry powder administered directly to the pulmonary system. Applicant's argument has been fully considered but found not to be persuasive. It is the

Examiners position that Laube et al. does teach that insulin is administered to lungs in an aerosolized form. It would have been obvious to one of ordinary skill in the art that the active micoparticles are formed into dry powder prior to aerosolization.

Applicant further argues that there is no motivation combine Milstein with Laube et al. Applicant's argument has been fully considered but found not to be persuasive. One would have been motivated to formulate the insulin formulation of Milstein into a aerosol because Laube et al. teach that pulmonary delivery is a much less discomforting means of delivery, particularly in contrast to subcutaneous injection as taught by Milstein.

Applicant finally argues that there is no reasonable expectation of success when combining the prior art references. Applicant's argument has been fully considered but found not to be persuasive. It is the Examiners position that Laube et al. teach how to aerosolize insulin compositions and Milstein teach a composition comprising insulin. Therefore, it would have been expected that one would be able to aerosolize the formulation taught by Milstein absent unexpected results. For the foregoing reasons the rejection of claims 23-26 and 40-49 under 35 U.S.C. 103(a) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616